HFL-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL – 9124-01
July 25, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David L. Zavagno
Chief Executive Officer
Women's Diagnostic Clinic, Inc.
24325 Lorain Rd.
North Olmstead, Ohio 44070

Facility I.D.#: 147736

Dear Mr. Zavagno:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on July 17, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

***Medical Records and Mammography Reports* - 21 CFR 900.12(c)(2)&(3)**

Your facility's system is inadequate in communicating to the patients and to the referring health care provider the results of their mammograms. Your facility's system fails to demonstrate that all of the mammography results will be communicated to the patients' health care provider and to provide to each of the patients a lay summary report within 30 days of the mammography examinations. Also your facility's standard operating procedure does not demonstrate that all of the suspicious or highly suggestive of malignancy findings are reported to the referring health care provider and to the patient as soon as possible.

On July 17, 2001, the inspector found a patient film jacket in a "holding bin" in the radiology department. The inspector was told that this patient film was in the "holding bin waiting for outside mammography films prior to interpretation. This patient had a mammogram performed at your facility on June 18, 2001. Your staff indicated to the inspector that they were not aware of the requirement to notify the health care provider and the patient of the results of the mammogram within 30 days of the date of examination. The inspector observed that your staff does not have a written policy of

reporting in writing to the health care provider and to the patient as soon as possible any case with suspicious or highly suggestive of malignancy findings.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to your staff at the close of the inspection. These Level 2 noncompliance items are:

1. Quality Assurance – *Equipment* - 21 CFR 900.12(e)(8)(i)&(ii) as further required in 21 CFR 900.12 (e)(2)

Your records revealed that your facility failed to document corrective actions before further mammography examinations, for failing image score, or a phantom background optical density or density difference found outside the regulatory limits.

During the inspection, the inspector observed the weekly phantom quality control results were out of limits at least six occasions between August 2000 to November 2000 and there was no documentation of corrective action taken.

2. Quality Standards –*Personnel – Interpreting Physicians* 21 CFR 900.12(a)(1)(iii)(B) & (a)(4)

Your staff failed to show documents verifying that the interpreting physician, [redacted] meets the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

During the inspection, the inspector observed your facility's records and found that [redacted] had read a total of 882 mammography examinations in a 24-month period prior to the date of the inspection.

3. Quality Assurance – *Mammography Medical Outcomes Audit* 21 CFR 900.12(f)(1)& (2)

Your staff failed to show that a medical audit and outcomes analysis was performed annually. Also your staff failed to show that a medical audit and outcomes analysis was performed individually and collectively for all interpreting physicians at your facility only.

4. Quality Assurance – *Mammography Medical Outcomes Audit* 21 CFR 900.12(f)(3)

Your staff failed to designate a reviewing interpreting physician for the purpose of evaluating your facility medical outcome audit to follow-up positive mammography cases.

5. Quality Assurance – *Mammography Medical Outcomes Audit* 21 CFR 900.12(f)(1)

Your staff was unable to show examples of or there was no attempt to obtain biopsy results for all of the positive mammogram cases.

During the inspection, the inspector observed your facility's records with many positive mammography cases with no documentation of obtaining the pathology results.

The other items listed in the July 17, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 items in your written response.

You must act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please send a copy to the State radiation control office:

Ms. Terri Eckert
Ohio Department of Health
Radiologic Technology Section
161 South High St., Suite 400
Akron, OH 44308

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

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OH/TEckert

Priscilla F. Butler, M.S.
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